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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,234	01/11/2002	Paola Elisabetini	DI-5782	8974

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BAXTER HEALTHCARE CORPORATION
RENAL DIVISION
1 BAXTER PARKWAY
DF3-3E
DEERFIELD, IL 60015

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,234

Applicant(s)

ELISABETTINI ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1, claims 1-16, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the Patent Office has not stated what classes/subclasses of the different inventions. This is not found persuasive because the fact that inventions may or may not be within the same class/subclass does not preclude a determination that the claims may properly be restrict. Notwithstanding the same, Examiner withdraws the restriction requirement and prosecutes claims 1-72.

Information Disclosure Statement

The information disclosure statement filed 9/23/2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the information disclosure statement filed fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The PTO-1449 lists a number of publications as foreign patent documents, however, translations, portions of patent documents or abstracts thereof do not constitute "a legible copy of each . . . foreign patent". It has been placed in the application file, but except for EP 0 209 607, EP 0 277 868, EP 0 278 100, 0 417 478, 0 437 274 and JP 11-9659 and the publications listed under "Other Documents", the information referred to therein has not been considered. Examiner requests, except for the foreign patents listed above, that Applicant either provide complete copies of each foreign patent listed or list the documents provided under, "Other Documents", indicating the source, date, pertinent pages, columns or paragraphs, etc..

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,5,11,15-19,24,28,29,44-47,52,55-57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watanabe et al. (US Pat 5,122,516).

Watanabe et al. expressly discloses a two part composition which are stored separately in which first composition contains sodium, potassium and the second composition contains sodium and bicarbonate which is used for blood dialysis falling within the scope of applicant's claims (Column 6, lines 13-68, Columns 7-10).

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Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980); *In re May*, 197 USPQ 601, 607 (CCPA 1978); *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (US Pat. 5,122,516) in view of Feriani et al. (US Pat. 4,630,727) and van Bommel et al..

Watanabe et al. teach a two part composition, the first composition which contains an acid pH adjusting agent and sodium and the second composition which contains sodium and bicarbonate, which are stored separately and used for blood dialysis (Column 6, lines 13-68, Columns 7-10). A preferred embodiment is taught in which potassium is listed as a component in first composition but not the second composition (Column 6, lines 13-68, Columns 7-10).

Feriani et al. teach a two part composition contained in a twin-chamber bag in which the first chamber is filled with a bicarbonate-containing fluid and the second chamber is filled with an acid fluid (Abstract, Figures 1,2). An embodiment is taught where potassium is listed as a component in the bicarbonate containing solution but is not listed in the acid fluid (Column 6, lines 15-44). It is taught that the composition may be used for dialysis, hemofiltration and infusion (Column 6, lines 54-55). It is taught that for safety reasons it is preferred to have the

bicarbonate in the compartment which has the discharge duct to prevent the acid part from being administered to the patient unmixed (Column 7, lines 3-21).

van Bommel et al. teach that hemodialysis and continuous renal replacement therapy can use the same fluids (Pgs. 271, Table 2, 272).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a two-part composition comprising potassium in both the bicarbonate part and electrolyte part. However, the prior art amply suggests the same as it is known in the art to have two-part compositions in which potassium is contained either in the acid/electrolyte part or the bicarbonate part. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. Further, it would have been well within the skill of one of ordinary skill in the art to have varying pH's in the bicarbonate part and acid/electrolyte part, including pH's falling within the claimed pH's, depending on the desired amounts of acid and bicarbonate in each part and the desired final pH of the mixture of the two parts. Also, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use a double chambered bag in which a first component cannot be administered to a patient without mixing with the second component for purposes of patient safety. Finally, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the two-part compositions for hemofiltration, including renal replacement therapy and infusion, with the expectation that the prior art dialysate composition would be suitable for the same.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

July 12, 2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600